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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of
Sharon F. Kleyne

Group Art Unit: 1619

Serial No. 09/614,790

Examiner: Michael Willis TECH CENTER 1600/2900

Filed: July 12, 2000

Tel. No. (703) 305-1679

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FEB 19 2002

For a Patent for
METHOD AND KIT FOR MOISTURIZING
THE SURFACE OF THE EYE

FIRST DECLARATION OF DR. RACHAEL GARRETT
37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir,

1. I, Rachael Garrett, OD, am a clinical optometrist working at the Oregon Health Sciences University. My resume is attached hereto. I am familiar with portions of the prosecution of this application.

2. I am submitting this Declaration in response to the contention of the Examiner that the Embleton reference, WO 97/23177, cited against the application discloses water as an ophthalmic treatment liquid.

3. Embleton discloses, on page 13, that ophthalmic treatment liquids that may be used in accordance with his invention include: "Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds. . ."

4. Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects. These essential ingredients include (a) tonicity agents such as dextran 40 and 70, glycerin, potassium glycol, and sodium chloride, (b) viscosity increasing agents, such as carboxymethylcellulose, dextran 70, gelatin, glycerin, hydroxymethylcellulose, poloxamer 407, polysorbate 80, propylene glycol, polyvinyl alcohol, an polyvinylpyrrolidone, and (c) wetting agents, such as polysorbate 20 and 80, poloxamer 282, and tyloxapol. Additionally, these formulations usually, but not necessarily, contain (d) preservatives, such as benzalkonium chloride, cetylpyridinium, thimerosal, methyl/propyl paraben, sodium benzoate, sodium propionate, and sorbic acid, and (e) antioxidants, such as EDTA, sodium bisulfite, sodium metabisulfite, sodium thiosulfate, and thiourea.

5. Therefore, it is my understanding that Embleton does not disclose the use of water, per se, as an artificial tear/dry eye therapy or comfort drop. Rather, my understanding is that Embleton discloses artificial tear/dry eye therapies and comfort drops that are based upon saline, water or oil, and which include other ingredients that are necessarily present in these formulations

6. It is my opinion that most eye care professionals, other than myself, would also understand the disclosure of Embleton as I have stated above.

Further, Deponent sayeth naught.

The undersigned declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

12/18/01

Date


Rachael Garrett, OD



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Curriculum Vitae

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Name: Rachael L. Garrett, O.D.

Present Position: Instructor, Department of Ophthalmology
Cornea Service and Vision Correction Center
Casey Eye Institute
Oregon Health and Sciences University

Office Address: Casey Eye Institute
3375 SW Terwilliger Blvd.
Portland, Oregon 97201
503-494-3981
503-494-3929 facsimile
garrettr@ohsu.edu

Home Address: 276 NW 11th Unit 108
Portland, Oregon 97209
503-241-6556
jrgdec94@aol.com

Biographical Information: Date of Birth: September 25, 1970, West Covina, California
Spouse: Jeffrey H. Garrett

Education: Doctor of Optometry "With Distinction"
Southern California College of Optometry, Fullerton, California
May, 1997

Bachelor of Arts, Biological Sciences
Hanover College, Hanover, Indiana
January, 1993

Specialty Certification: Optometric Residency, Hospital based/Primary care, Geriatric Optometry
Sepulveda Veterans Affairs Medical Center, Sepulveda, California
July, 1998

Professional Licensure: State of California, 10933T (diagnostic and therapeutic certification)
State of Oregon, 2713T (diagnostic and therapeutic certification)

**Clinical/
Optometric
Experiences:**

Optometrist, Casey Eye Institute, Oregon Health Sciences University,
Portland, Oregon, February, 1999-present

Optometrist, Laser Eye Center, Ontario, California,
July, 1998-January, 1999

Clinical Instructor, Cornea and Contact Lens Service, Optometric Center
of Fullerton, Fullerton, California, August, 1997-July, 1998

Optometric Resident, Sepulveda Veterans Affairs Medical Center,
Sepulveda, California, July, 1997-July, 1998

Optometric Intern, Optometric Center of Fullerton, Fullerton, California,
July, 1995-May, 1996 and February, 1997-May, 1997

Optometric Intern, Developmental Optometry Group, Newport,
California, November, 1996-February, 1997

Optometric Intern, Optometric Center of Los Angeles,
Los Angeles, California, August, 1996-November, 1996

Optometric Intern, Santa Barbara Veterans Affairs Outpatient Clinic,
Santa Barbara, California, May, 1996-August, 1996.

Tutor, Treatment and Management of Ocular Disease
Southern California College of Optometry, Fullerton, California,
January, 1997-May, 1997

Teaching Assistant for Dr. John Nishimoto, Ocular Disease Case Analysis.
Southern California College of Optometry, Fullerton, California.
March, 1997-May, 1997

Teaching Assistant, Arizona Optometric Association, Continuing
Education Courses, Phoenix, Arizona, June, 1996

Teaching Assistant for Dr. David Kirschen, Binocular Vision and Sensory
Perception, Southern California College of Optometry, Fullerton, California.
February, 1996-May, 1996

Teaching Assistant for Dr. John Nishimoto, Introduction to Optometric Case
Analysis, Southern California College of Optometry, Fullerton, California.
November, 1995-February, 1996

Appointments:

President, Portland Metropolitan Optometric Society, 2001-Present

Member, Third Party Committee, Oregon Optometric Physicians Association, 2001- Present

Board of Directors, Portland Metropolitan Optometric Society, 1999-Present

Adjunct Assistant Professor, Pacific University College of Optometry, Forest Grove, OR, 1999-Present

Director, Comanagement Services, Casey Eye Institute, Vision Correction Center. 1999-Present

Membership Development Task Force, American Academy of Optometry. 1997-1998

Class of 1997 Chair, Young Alumni Committee, Southern California College of Optometry, 1997-1998

American Optometric Student Association National Student Liaison to the American Academy of Optometry, 1996-1997

Curriculum Committee, Southern California College of Optometry, 1996-1997

Editor, Study Guide for the National Board of Examiners in Optometry. Southern California College of Optometry. 1995-1996

SCCO Student Liaison to the American Academy of Optometry, 1994-1996

Professional Organizations:

Oregon Optometric Physicians' Association, 1999- Present

American Academy of Optometry, Fellow. 2000- Present

American Optometric Student Association/ American Optometric Association, 1993- Present

American Academy of Optometry Student Member, 1994-1998

Beta Sigma Kappa International Optometric Honor Society. 1994-1997

American Public Health Association, 1994-1995

Research:

Garrett RL, Rich LF, Mathers WD. 2001. Measurement of Flap Thickness with Confocal Microscopy (in process). Garrett RL. 2001. Posterior Corneal Changes Post LASIK (in process).

Mathers WD, Waikom, B, Garrett, RL. 2000. The Effects of Laser in situ keratomileusis on tear film and corneal sensitivity (in process).

Garrett, RL, Housman, CL, Schornack, JA. 1996. The Effects of Multivitamins and Topical Vitamin A on the Tear Film of Presbyopic Soft Contact Lens Wearers. Senior Research Project, Southern California College of Optometry.

Presentations:

Herpes Simplex Keratitis Post-LASIK, Refractive Surgery Case Conference, Casey Eye Institute, Portland, OR 2001

Posterior Corneal Changes Following LASIK, Vision 2001, Casey Eye Institute, Portland, OR 2001.

Cornea and Refractive Surgery Update, Optometric Continuing Education Course, Casey Eye Institute, Portland, OR 2001.

Garrett, RL. Corneal Topography in Refractive Surgery. Class of 2002, Pacific University College of Optometry, Forest Grove, Oregon, 2001

Garrett, RL. Topography Pearls, Refractive Surgery Case Conference, Casey Eye Institute, Portland, OR 2001

Mathers, WD, Garrett, RL. Applications of Confocal Microscopy in Refractive Surgery, Portland Metropolitan Optometric Society Monthly Meeting, Casey Eye Institute, Portland, Oregon 2001

Garrett, RL. LASIK and Dry Eye, Oregon Ophthalmological Alumni Association- 55th Annual Alumni Meeting, Casey Eye Institute, Portland, Oregon 2000

Garrett, RL. Physical Optics, Resident's Lecture Series. Casey Eye Institute, Portland, Oregon, 2000

Garrett, RL. Geometrical Optics I, Resident's Lecture Series, Casey Eye Institute, Portland, Oregon, 2000

Garrett, RL. Geometrical Optics II, Resident's Lecture Series, Casey Eye Institute, Portland, Oregon, 2000

Presentations: Garrett, RL. Clinical Refraction- Subjective Refraction, Resident's Lecture Series, Casey Eye Institute, Portland, Oregon, 2000
(Continued)

Garrett, RL. Preoperative Risks...Postoperative Realities, Continuing Optometric Education Course, Casey Eye Institute, Portland , Oregon, 2000

Garrett, RL, Rich LF. Updates in Refractive Surgery, Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Optics of Excimer Lasers. Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Pre and Postoperative Applications of Corneal Topography. Class of 2000, Pacific University College of Optometry, Forest Grove, Oregon, 2000

Garrett, RL. Treatment of Astigmatism with the Excimer Laser. Refractive Surgery Case Conference, Casey Eye Institute, Portland, Oregon 2000

Garrett, RL. Corneal Topography and the Vision Correction Patient. Cross Talk Faculty Education Series, Pacific University College of Optometry, Forest Grove, Oregon, 1999

Garrett, RL. Treatment of Central Islands. Refractive Surgery Case Conference, Casey Eye Institute, Portland, Oregon 1999

Garrett, R.L. Cornea and Refractive Surgery Update. Continuing Optometric Education Course, Casey Eye Institute. Portland . Oregon. 1999

Garrett, RL. Corneal Topography and the Excimer Laser Patient. Oregon Ophthalmological Alumni Association- 54th Annual Alumni Meeting, Casey Eye Institute, Portland, Oregon 1999

Garrett, R.L. Pre and Postoperative Care of the Excimer Laser Patient Columbia Gorge Seminar- Cataract, Cornea and Refractive Surgery Update, Casey Eye Institute, Portland , Oregon, 1999

Garrett, R.L. Innovative Changes in Refractive Surgery. Class of 1999, Pacific University College of Optometry, Forest Grove, Oregon, 1999

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Poster Presentation, American Academy of Optometry, San Francisco, California, 1998

Presentations:
(Continued)

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Continuing education course, Southern California College of Optometry, Fullerton, California, 1998

Garrett, RL. Conjunctival and Corneal Dysplasia, Carcinoma in situ and Invasive Squamous Cell Carcinoma. Fourth year student block lectures, Southern California College of Optometry, Fullerton, California, 1998

Garrett, RL, Housman, CL, Schornack, JA. The Effects of Multivitamins and Topical Vitamin A on the Tear Film of Presbyopic Soft Contact Lens Wearers. Poster Presentation, American Academy of Optometry, Orlando, Florida, 1996

**Awards
and Honors:**

Hedda Jaanus Podrang Memorial Scholarship Fund, 1997

Dr.'s Robert L. Gordon & Andrea C. Silvers Award, 1997

Dr. Roy and Mrs. Lynn Smith Scholarship Award, 1996

Vision Service Plan Independent Practice Award, 1996

Wesley-Jessen Student Travel Fellowship Award, 1996

Beta Sigma Kappa Research Grant, 1996

Southwest Contact Lens Society Award, 1995

Bausch and Lomb Student Leadership Award, 1995